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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,805	02/16/2001	George V. Guittard	ARC 2366N1	4150

7590

03/13/2002

Paul L. Sabatine
ALZA Corporation
950 Page Mill Road
P.O. Box 10950
Palo Alto, CA 94303-0802

EXAMINER

WILLIAMSON, MICHAEL A

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/785,805

Applicant(s)

GUITTARD ET AL.

Examiner

Michael A. Williamson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other: _____

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DETAILED ACTION

Pending Claims

The pending claims in the instant application are 1, 32 and 33. The independent claims are 1 and 32.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 32 and 33 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for oxybutynin and its pharmaceutically acceptable salt in an amount of 240 ng to 650 mg that is controlled and sustained, zero order release, but does not reasonably provide enablement for oxybutynin and its pharmaceutically acceptable salt has been maintained for reasons of record in paper number 3, paragraph 2.

Double Patenting

2. The rejection of claims 1, 32 and 33 under the judicially created doctrine of double patenting over all claims of U. S. Patent Nos. 5,674,895, 5,840,754, 5,912,268 and 6,262,115 since the claims, if allowed, would improperly extend the "right to

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exclude" already granted in the patent has been maintained for reasons of record in paper number 3, paragraph 4.

Response to Arguments

3. Applicant's arguments filed January 18, 2002 have been fully considered but they are not persuasive.

Applicant argues that the claims have been amended to disclose the range of oxybutynin and its pharmaceutically acceptable salts and the release period disclosed (see page 3, 2nd full paragraph). Applicant has not amended the claims in accordance with the rejection of record which states that the composition be: (1) in an amount of 240 ng to 650 mg and (2) controlled and sustained, zero order release (3) both in a 24 hr. period. Applicant's final argument is that the claims are in rejected status therefore a terminal disclaimer was not filed (see page 3, 5th full paragraph). The double patenting rejection is independent of the other rejections of record.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

5.

Crystal Mall 1 Facsimile Center

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

6. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.



Michael A. Williamson
Patent Examiner
Group 1610

Williamson010630
March 10, 2002